AUG 0 3 2009 K091333

Attachment 2 – 510(k) Summary

510(k) SUMMARY

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	May 5, 2009	
Device:	Trade Name:	S-Test LDL Reagent cartridge
	Classification:	Class I Exempt
	Common/Classification Name:	Low Density Lipoprotein Cholesterol Test System (21 C.F.R. § 862.1475) Product Code MRR
Predicate Devices:	Manufacturer for analyzer/reagent system predicate: Alfa Wassermann ACE plus ISE/Clinical Chemistry System ACE Low Density Lipoprotein Cholesterol Reagent (K991733)	
Device Description:	The S-Test Low Density Lipoprotein (LDL) Cholesterol reagent cartridges, used with the S40 Clinical Analyzer, are intended for quantitative *in vitro* diagnostic determination of LDL cholesterol concentrations in serum or heparin plasma based on a photometric test measuring the formation of a reddish purple complex in a coupled enzymatic reaction.	
Intended Use:	The S-Test Low Density Lipoprotein Cholesterol Reagent is intended for the quantitative determination of LDL concentration in serum or heparin plasma using the S40 Clinical Analyzer. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.	
Technological Characteristics:	The S-Test LDL Reagent is contained in a bi-reagent cartridge. Reagent 1 contains 4-aminoantipyrine, cholesterol esterase, cholesterol oxidase, peroxidase, and a surfactant in Good's buffer. Reagent 2 contains a different surfactant, N,N-bis (4-sulfobutyl)-m-toluidine, disodium salt in Good's buffer.	

Performance Data:	Performance data on the S-Test LDL reagent included precision, accuracy, sensitivity data and matrix comparison data. Precision: In testing at three LDL levels for 22 days, the within-run CV ranged from 1.2 to 2.2%, and total CV ranged from 2.2 to 2.5%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.8 to 2.8% and total CV ranged from 1.2 to 2.8%. Accuracy: In a correlation study, 110 serum samples with LDL values ranging from 11 to 388 mg/dL were assayed on the S40 Clinical Analyzer using S-Test LDL (y) and a comparative method (x). Least-squares regression analysis yielded a correlation coefficient of 0.996, a standard error estimate of 6.6, a confidence interval slope of 0.948 to 0.982, and a confidence interval intercept of -1.7 to 3.4. In patient correlation studies at three separate POL sites using the S40 Clinical Analyzer and a comparative method, least-squares regression analysis yielded correlation coefficients of 0.995 to 0.997, standard error estimates of 6.0 to 8.0, confidence interval slopes of 0.895 to 0.967, and confidence interval intercepts of -4.6 to 13.6. Sensitivity: The detection limit was 1 mg/dL. Serum vs. Plasma: A study was performed by running LDL determinations on 34 paired samples drawn from the same patients in serum and lithium heparin plasma tubes. The use of plasma was confirmed in a matrix comparison study using the paired t-test for means: Range: 13 to 350 mg/dL (serum), t-Statistic = 1.71, t-Critical value 2.03 at $\alpha = 0.05$, not statistically significant.
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Alfa Wasserman, Inc.
c/o Mr. Hyman Katz
Vice President, Quality & Regulatory Affairs
4 Henderson Drive
West Caldwell, NJ 07006

AUG 03 2009

Re: k091333
Trade Name: S-Test LDL Cholesterol (LDL)
Regulation Number: 21 CFR §862.1475
Regulation Name: Lipoprotein test system.
Regulatory Class: Class I
Product Codes: MRR
Dated: May 5, 2009
Received: May 6, 2009

Dear Mr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K091333

Device Name: S-Test Low Density Lipoprotein (LDL) Cholesterol

Indication For Use: The S-Test Low Density Lipoprotein Cholesterol Reagent is intended for the quantitative determination of LDL concentration in serum or heparin plasma using the S40 Clinical Analyzer. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091333